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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,289

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

03/28/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/531,289	Applicant(s) UEHARA ET AL.	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 19, 20, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 19, 20, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/07; 10/06; 6/06; 1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment and response filed January 28, 2008 have been received.
2. Claims 16, 19, 20, 25 and 26 are currently pending.
3. Applicant's reply to the restriction requirement is noted. However, the previous restriction requirement was erroneous and is replaced by the following restriction requirement.

Election/Restrictions

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

One, or two or more medicinal ingredients selected from the group consisting of Glycyrrhiza glabra extract, Coix lachryma-jobi extract, blackcurrant fruit extract, Inula britannica extract, cranberry fruit extract, Mucuna birdwoodiana extract, cactus extract, Momordica grosvenorii extract, and astaxanthin and its derivatives.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 16, 19, 20, 25 and 26

The following claim(s) are generic: all.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the different species is drawn to a distinct plant extract composition. Thus, each of the species does not have a common structural element. Therefore, a person of ordinary skill in the art would not expect these distinct plant extract compositions to function equivalently. Thus, the different species lack unity.

5. During a telephone conversation with Mr. Arnold Turk on March 18, 2008 a provisional election was made with traverse to prosecute the invention of *Glycyrrhiza glabra* extract for the species. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Claims 16, 19, 20, 25, and 26 are examined on the merits solely in regards to the elected species.

Claim Objections

7. Claim 16 is objected to because of the following informalities: at the beginning of line 3 there is an erroneous ")". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 19 and 20 are indefinite due to improper Markush language. The claims state that the plant is selected from the group consisting of Cistaceae "including" *Cistus ladaniferus*...etc. The use of "including" in this context is improper because it implies that the Markush group can contain other members other than those specifically recited. However, the claims do not define what these members might be. Therefore, the scope of the claims is indefinite.

Claims 19 and 20 are also indefinite because the identity of "*Cistus monoperiensis*" is indefinite. A search of this plant species did not produce any results other than applicant's own work. Thus, it is unclear if this plant species is a newly discovered plant species or if this is a misspelling of a common plant species. Applicant's previous work that recite this species do not help to clarify this issue because they do not state that the plant material is available to the public.

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9. Claim 20 is indefinite because it is unclear what the claim is attempting to claim. It is unclear if the claim is requiring an additional ingredient in the form of the recited plant extracts or if the claim is defining the source of ingredient (A) in claim 16. Clarification is needed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the plant *Cistus monoperiensis* is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plant seeds. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific plant has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 16, 19, 20, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamai (US 6,313,214) and Hadas (US 5,609,875).

Tamai teaches the compounds claimed as ingredient (A), formula 1. The reference teaches that these compounds can be extracted from the plants claimed in claims 19 and 20. The reference teaches that these compounds are used to treating skin aging by lightening the skin (see claims, column 1, lines 21-28, and column 2, line 57-end). The reference does not teach using Glycyrrhiza glabra extract in the composition.

Hadas teaches using Glycyrrhiza glabra extract for lightening the skin (see claims).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that lighten the skin. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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Based on the disclosure by these references that these substances are used in compositions to lighten the skin, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to lighten the skin. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186. Since Tamai teaches that skin lightening preparations are useful in treating skin aging, an artisan of ordinary skill would reasonably expect that using the skin lightening preparation taught by Tamai and Hadas to treat skin aging would be successful. This reasonable expectation of success would motivate the artisan to treat skin aging using the combination of ingredient (A) and *G. glabra*.

It is noted that pages 62 and 63 of applicant's specification contain data that the specification states shows synergistic results for the combination of ingredient (A) and *G. glabra* extract. However, these results are not considered to show synergistic results. The results (Table 2-1) appear to be qualitative judgments rather than quantifiable data. As discussed in MPEP section 716.02(b), the burden is on the applicant to show how offered data is of statistical significance. The qualitative data do not appear to be of statistical significance. Furthermore, it is unclear if the qualitative increase in skin whitening judged for the combination of the two ingredients is synergistic rather than additive (see MPEP section 716.02(a)). Since both ingredients are known to be able to whiten the skin, it is not unexpected that a combination of these two ingredients would produce a larger whitening effect than each alone. Furthermore,

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even if the results did show synergism, the results are only shown for one amount of each ingredient. These results are not considered to be commensurate in scope with the broadly claimed composition which does not require any specific amounts (see MPEP section 716.02(d)). Therefore, the claimed invention is considered to be proper rendered obvious by the combination of the references.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655